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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,777

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Allan Tanghoej

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EXAMINER

SU, SUSAN SHAN

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,777	<b>Applicant(s)</b> TANGHOEJ, ALLAN	
	<b>Examiner</b> SUSAN SU	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1-20 are pending, of which Claim 1 (the sole independent claim) has been amended and Claim 20 is new. All claims are examined on the merits.

### ***Claim Objections***

1. Claim 19 is objected to because of the following informalities: lack of antecedent basis for "the receptacle". It is believed that Claim 19 is dependent on Claim 17 instead of Claim 16. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-7, 9-12, & 20 are rejected under 35 U.S.C. 103(a) as being obvious over Christopher (US 4,571,241).

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With regard to Claims 1, 4, 5, & 7, Christopher teaches a device for opening a human bladder comprising:

an oblong member (40 & 14) for opening the urethral sphincter, said oblong member being configured to drain fluid from the bladder; and

a guide member (30) for manipulating the oblong member, at least a part of the guide member being made of an elastically deformable material flexible enough to be bent into a first configuration and then unfolding from said first configuration into a second configuration in which said guide member is sufficiently rigid in a longitudinal direction to be used to insert the oblong member into a urinary tract without buckling under longitudinal pressure associated with insertion.

Christopher does not explicitly teach a rolled or folded first configuration for the guide member (Col. 4 lines 3-11), but since the guide member disclosed by prior art is plastic and flexible enough to follow the contours of the urethra, it is capable of being bent or rolled in an essentially elastic formation. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Christopher for the purpose of storing the guide member in a configuration that makes it easier to transport.

With regard to Claims 2 & 3, Christopher also teaches that a cross-sectional area of a major part of the guide member is substantially smaller than a cross-sectional area of the oblong member in both the first and second configurations (the cross-sectional area of the guide member does not change).

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With regard to Claims 6 & 15, Christopher does not expressly teach that the device is packed in a first configuration and the guide member unfolds upon unpacking. However, Christopher discloses that the guide member is flexible to fit contours yet rigid enough to maintain its shape, and the same goes for a part of the oblong member (col. 4 lines 40-43). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Christopher by packing it in a folded configuration for the purpose of making the device more easily transportable and to keep the device free from contaminant prior to use.

With regard to Claims 9-10 & 12, Christopher also teaches a slack tube (16), the slack tube being less rigid than the oblong member (as can be seen in Fig. 2 by the collapse of the slack tube 16 compared to the oblong member 40 & 14) and that the slack tube and the oblong member are provided in one piece (see Figs. 2 & 3). Christopher further teaches that the slack tube includes a gripping element (any part of its edge that extends farthest away from the bladder), allowing the user to grip the slack tube for removing the oblong member from a urinary canal (since the slack tube and oblong member are joined, pulling on the slack tube will also pull out the oblong member).

With regard to Claim 11, Christopher does not teach that the slack tube is longer than the guide member. However, modifying the size/length of a tube requires only routine skills in the art. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Christopher for the purpose of allowing the urine to be drained inside the slack tube into a collection container (if the guide member is

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longer than any container attached to the slack tube would have an outlet to allow the guide member to pass through and allow for urine to leak outside the container).

With regard to Claim 20, Christopher also teaches that the guide member is connected to one end of said oblong member and is in substantially linear alignment therewith (when the guide member is used in inserting and removing the oblong member, it comes in contact with the distal end of the oblong member and therefore is considered to be connected, see Col. 4 lines 62-64).

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Christopher in view of Eshel et al. (US 5,916,195, "Eshel"). Christopher does not expressly teach that the guide member includes a gripping element. Eshel teaches a guide member (3) for insertion of a urinary drainage tube wherein the guide member includes a gripping element (39). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Christopher with Eshel for the purpose of easily holding and manipulating the guide member.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Christopher in view of Lambert (US 4,487,808). Christopher does not teach that at least part of the device is provided with a hydrophilic surface. Lambert teaches a hydrophilic coating used for medical devices such as urinary catheters (Col. 3 lines 49-54). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Christopher with Lambert for the purpose of making the insertion more comfortable for the patient.

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7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Christopher in view of Tihon (US 5,562,622). Christopher does not teach that the oblong member is solid. Tihon teaches a urinary drainage device with an oblong member (12, see Figs. 1a & 2) that is solid. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Christopher with Tihon for the purpose of forming an oblong member with more rigidity that allows for easier insertion.

8. Claims 16 & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christopher in view of Haacke et al. (US 2002/0123739, "Haacke"). Christopher does not teach a guiding device or a sealing element. Haacke teaches a guiding device (13) with a compartment (empty space inside 19) for guiding drained urine, the guiding device being adapted to convey an oblong member (10) from the compartment and into a urinary canal. Haacke also teaches a sealing element to seal between the compartment and the urinary canal (the exterior part where handle 15 joins to sliding hose 12). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Christopher with Haacke for the purpose of helping to align the drainage device for a quicker and painless insertion and to have an anchor abutting the urinary canal entry to provide more stability during the procedure.

9. Claims 17 & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christopher and Haacke as applied to Claim 16 above, and further in view of Kubalak (US 2002/0103467). Christopher and Haacke do not expressly teach a receptacle. Kubalak teaches a receptacle for use in urinary catheter systems. Kubalak also

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teaches that the receptacle is formed of a flexible material that allows the manipulation of the device through a wall of the receptacle ([0004]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Christopher and Haacke with Kubalak for the purpose of allowing for easier clean-up. After the modification, the receptacle would be in fluid communication with the compartment of the guiding device because the guiding device acts in part as a urine collection tube.

### ***Response to Arguments***

10. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment to the claim.

### ***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 8:30AM-6:00PM EST (alternate Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/  
Examiner, Art Unit 3761

/Tatyana Zalukaeva/  
Supervisory Patent Examiner, Art Unit 3761